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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,168	02/23/2004	Joseph R. Testa	0492611-0476 (MIT 9700)	8498

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,168	TESTA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Antisense targeting human APPL nucleic acid and methods of use:

i. Claims 4, 24, drawn to antisense (SEQ ID NO: 1) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.

ii. Claims 5, 25, drawn to antisense (SEQ ID NO: 2) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.

iii. Claims 6, 26, drawn to antisense (SEQ ID NO: 4) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.

It is noted that claims 1-3, 7-23, 27-33 are considered to link the above inventions.

Invention groups i-iii are considered patentably distinct inventions since they are drawn to antisense compositions (and methods of use) comprising distinct nucleotide sequence structures. The search of each of these antisense compounds are non-coextensive, therefore a separate search and consideration of the prior art is required for each of the above inventions.

II. double-stranded RNA targeting human APPL nucleic acid and methods of use:

i. siRNA and methods of use: claims 35, 37 (SEQ ID NO: 6), 39, 41-42, 45-46, 49-50, 53-60.

ii. shRNA and methods of use: claims 36, 38 (SEQ ID NO: 8), 40, 43-44, 47-48, 51-52, 61-68.

Claim 34 is a linking claim for the above inventions.

Invention groups i-ii are considered patentably distinct inventions since they are drawn to patentably distinct double stranded RNA compounds (and methods of use) comprising distinct nucleotide sequence structures. The search of each of these dsRNA compounds are non-coextensive, therefore a separate search and consideration of the prior art is required for each of the above inventions.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are patentably distinct since they are drawn to distinct chemical compounds, specifically antisense (SEQ ID NOs: 1, 2, and 4), and double stranded RNA (SEQ ID NO: 6 and 8) compounds. Each of these compounds comprise a distinct chemical structure, and require a separate search and consideration of the prior art. Antisense compounds may include both DNA and RNA oligonucleotides, however

dsRNA are comprised of RNA. Each of these sequences comprise a distinct nucleotide sequence as well. The antisense compounds of the invention include those having a sequence according to SEQ ID NO: 1, 2, and 4, and the dsRNA compounds of the invention include those that have a sequence according to SEQ ID NO: 6 and 8. Furthermore, antisense compounds are functionally distinct from dsRNA compounds since they inhibit the expression of their target nucleic acids by distinct molecular pathways.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species: a) human cells: selected from skeletal muscle, heart, ovary, and pancreas; b) a plurality of anti-cancer agents selected from cisplatin, carboplatin, herceptin, taxol, taxane derivatives, cyclophosphamide, methotrexate, vincristin, and etopside. The species are independent or distinct because a) the various human cells recited in the instant claims are patentably distinct as they are directed to distinct classes of cells which are known in the art to express a distinct set of genes and express a distinct set of molecular markers. The search of each of these individual classes of cells requires a separate search and consideration of the prior art. Furthermore, the various anti-cancer compounds listed in the claims are structurally distinct chemical compounds that require a separate search and consideration of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-68 are generic to the disclosed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE